

# Testimony of Dr. Charles King III

# Slide 1: Opinions

- Marketing and promotional efforts contributed to off-label sales of Neurontin
- Off-label sales of Neurontin would have continued even if Pfizer had stopped off-label promotion
- Off-label marketing influenced substantially all physicians prescribing Neurontin
- Suppression of serious adverse events enabled off-label sales of Neurontin

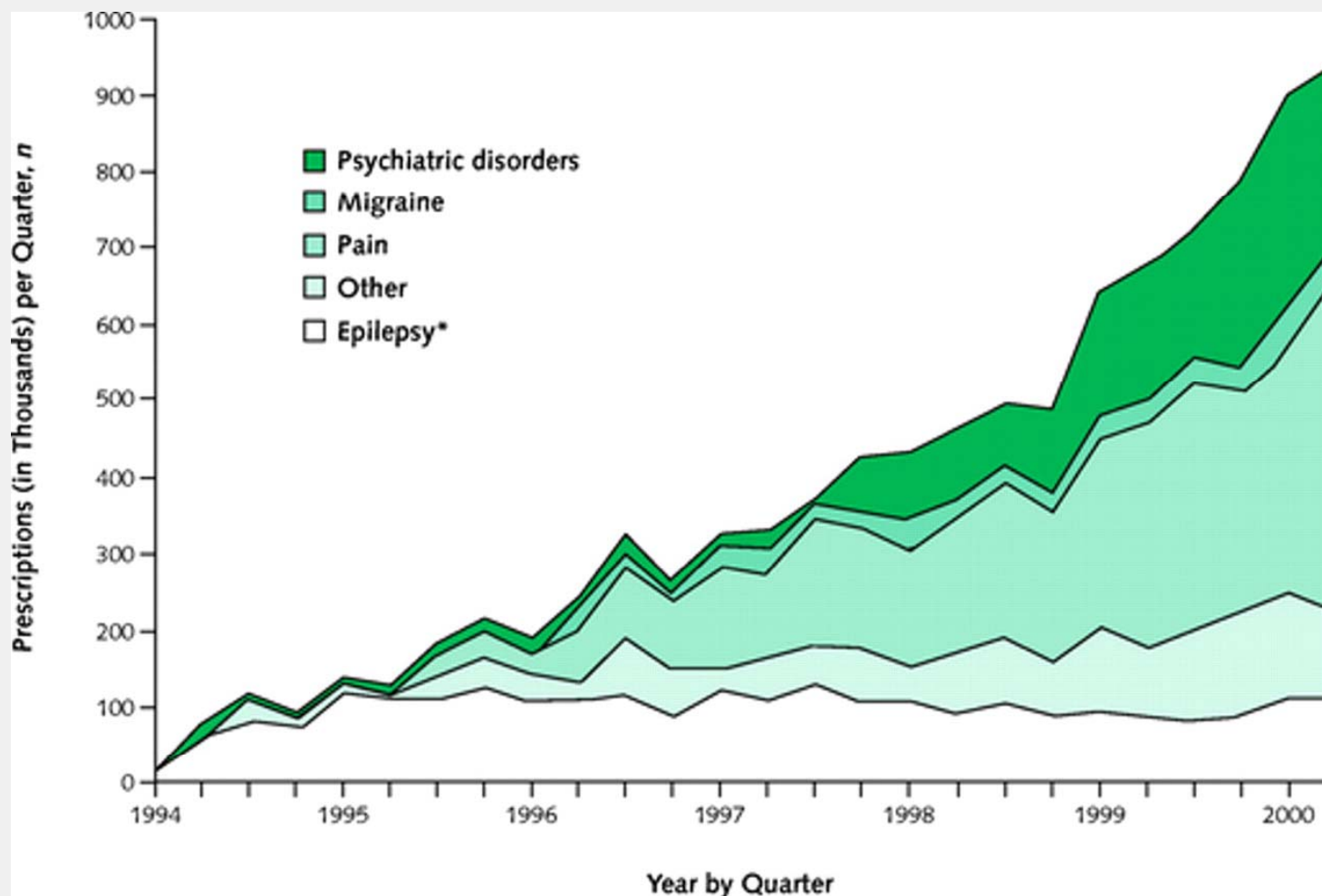
## Slide 2: The FDA Approves Drugs

- Drugs are approved only for specific uses
- Neurontin was approved ONLY for:
  - Adjunctive therapy for epilepsy (1993)
  - Adjunctive therapy for epilepsy for pediatric use (2000)
  - Post-herpetic neuralgia (2002)
- Neurontin was NEVER approved for the treatment of pain
- Neurontin is only approved for dosages up to 1800 mg/day

## Slide 3: Neurontin and Off-Label Sales

- Warner-Lambert began selling Neurontin in January 1994
- Projected lifetime sales of Neurontin were forecast to be only \$500 million
- Actual lifetime sales of Neurontin were greater than \$10 billion

## Slide 4: Neurontin Prescriptions by Diagnostic Category



Prescriptions for gabapentin, by diagnostic category. Estimates of diagnosis-linked prescribing provided by Pfizer, Inc.

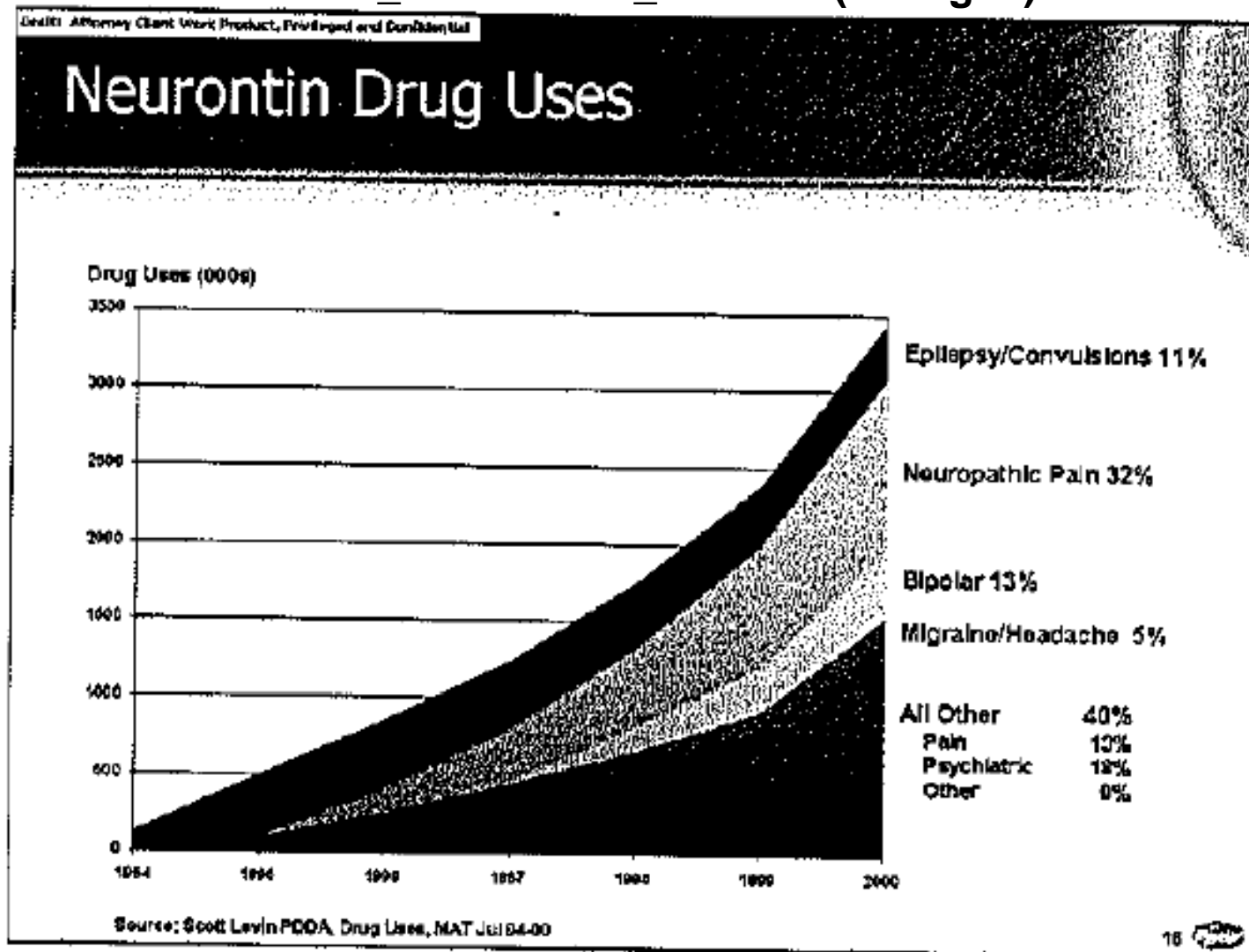
Source: Steinman *et al.*, *Annals of Internal Medicine*, 145(4), 2006, pp. 284-294.

**Annals of Internal Medicine**

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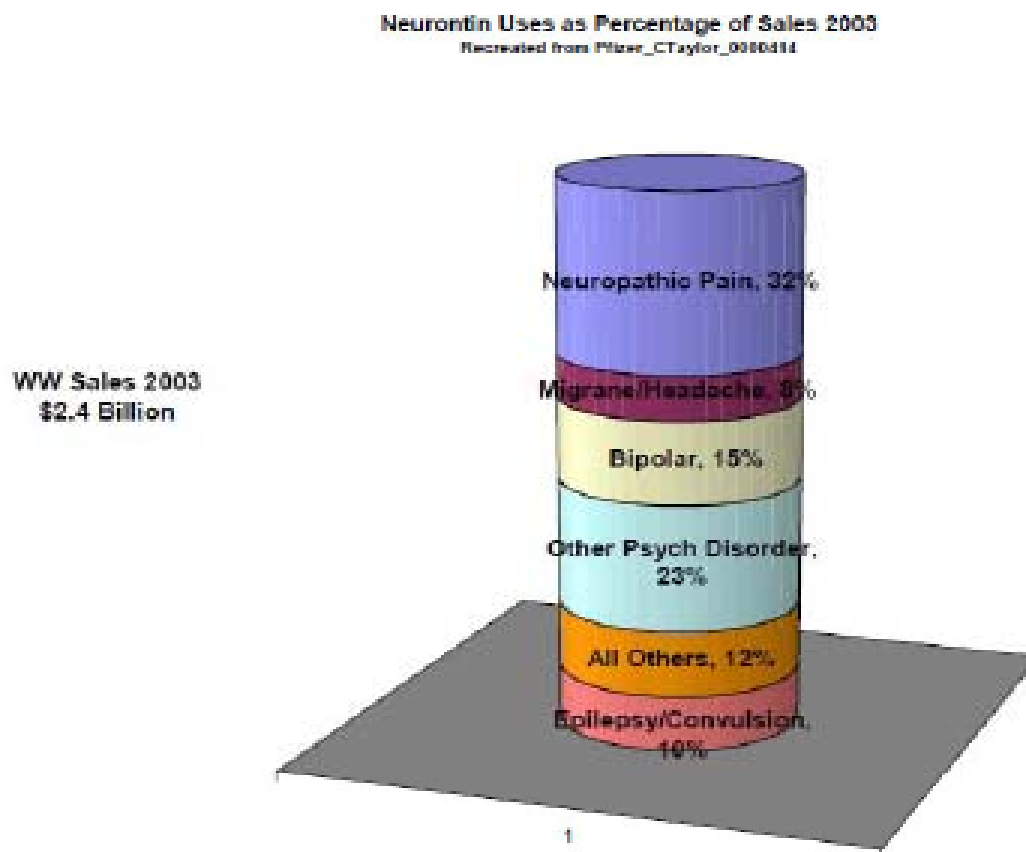
# Slide 5: Neurontin Uses by Diagnostic Category

Pfizer\_RGlanzman\_0000665 (enlarged)



## Slide 6: Off-Label Sales

- Off-label sales of Neurontin grew
  - From 15 % of all sales in 1994
  - To 90 % in 2003



## Slide 7: Academic Study by Radley et al.

Neurontin “had the highest proportion of off-label prescriptions” among 160 commonly prescribed drugs and “only 20% of its off-label use had strong support [for its clinical efficacy] compared with 80% with limited or no support.”



## Slide 8: Off-Label Uses as a Percentage of Total Uses

### % Off-Label Uses

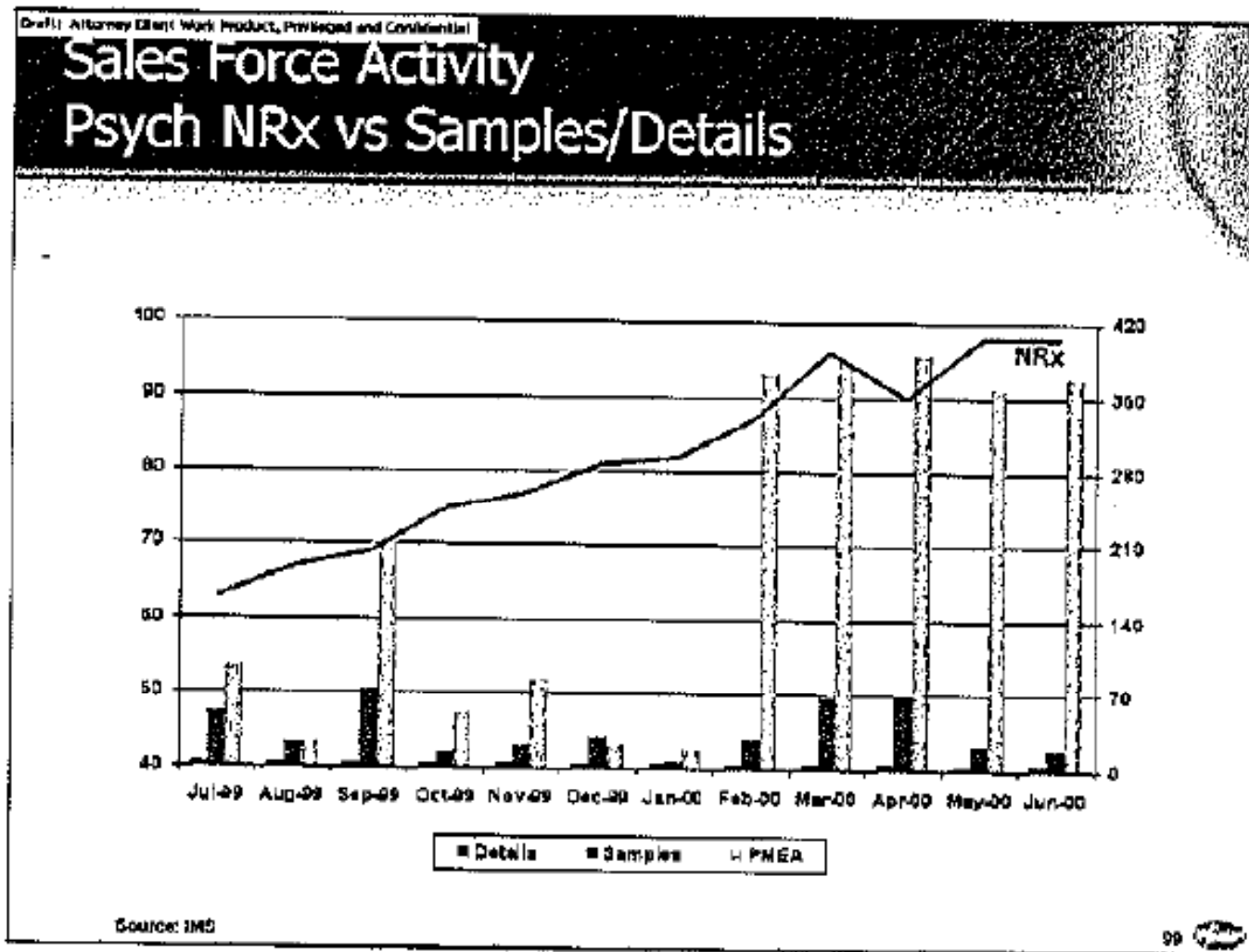
Neurontin Before Off-Label Marketing (1994)	15%
Average Among Commonly Prescribed Drugs	21%
Neurontin After Off-Label Marketing (2003)	90%

## Slide 9

Warner-Lambert and Pfizer  
marketed Neurontin for  
off-label use

# Slide 10: Promotional Efforts Targeted Psychiatrists

Pfizer\_RGlanzman\_0000748 (enlarged)



## Slide 11: Warner-Lambert Business Plan

“Medical education drives this market!!”

## Slide 12

Pfizer continued the off-label promotion  
initiated by Warner-Lambert

## Slide 13: Conclusions

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